Inspection report on compliance with HTA licensing standards
Inspection date: **14 August 2023**

Croydon Health Services NHS Trust

HTA licensing number 12305

Licensed under the Human Tissue Act 2004

Licensed activities

The table below shows the activities this establishment is licensed for and the activities currently undertaken at the establishment.

Area	Making of a post-mortem examination	Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation	Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Hub site **Croydon Health Services NHS Trust**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*

Summary of inspection findings

The HTA inspection for Croydon Health Services NHS Trust ('the establishment') identified one critical, 11 major and four minor shortfalls against standards for Consent, Governance and quality systems and Premises, facilities and equipment.

Three of the shortfalls (one critical and two major) relate to findings from the last inspection in 2018. The HTA is concerned that adequate steps were not taken to address these findings in the intervening period and to embed suitable practices at the establishment.

In light of the level and scope of shortfalls identified, the HTA is not assured that the current Designated Individual (DI) is suitable to comply with the duties set out under Section 18 of the Human Tissue Act 2004.

Following the inspection and in response to feedback, the establishment has made an application to vary the DI.

Compliance with HTA standards

Critical Shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	Although there is a consent policy in place, the consent policy does not reflect the requirements of the Human Tissue (HT) Act and the Human Tissue Authority's (HTA) codes of practice.	**Cumulative Critical**
b) There is a documented standard operating procedure (SOP) detailing the consent process	There is no documented standard operating procedure (SOP) in place for those seeking consent for perinatal/paediatric and adult post mortem (PM) examinations.	
c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	The consent seeker guidelines used by maternity staff do not fully reflect the requirements of the HT Act and the HTA's code of practice. The information refers to the HTA's old codes of practice (which were updated in 2017), and out of date contact details for the establishment conducting the licensed activity.	
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		

a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	There is no training in place. At the time of the inspection the DI was unsure if staff in the early pregnancy unit were aware that training should be undertaken to seek consent for perinatal PM examination. The establishment cannot be assured of the consent wishes of the family. This poses a risk that deceased may be stored and transferred for PM examination without appropriate consent. *(as a result, standards C2 (b), (c) and (d) cannot be assessed.)* *This shortfall was identified at the previous inspection in 2018.*	

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	Some SOPs relating to mortuary activities are not reflective of current practice or do not contain sufficient details of procedures. For example: • viewing of deceased. • release of deceased. • body condition checks of the deceased. Not all SOPs include all practices that are undertaken by staff. These include, but are not limited to, SOPs detailing the process for: • same or similar name of deceased. This is not an exhaustive list of the amendments required to all the SOPs and, to fully address this shortfall, the establishment should review all SOPs relating to all mortuary activities to ensure that they are accurate, reflect current practice, cross reference the appropriate SOPs and contain sufficient detail of procedures.	**Major**

b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed	There are three visiting pathologists, only one of whom conducts an external examination of the deceased prior to evisceration by mortuary staff. *This shortfall was identified at the previous inspection in 2018.*	**Major**
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The inspection team's audit found that the establishment's procedure for checking and documenting the condition of the deceased is not followed consistently, or at sufficiently regular intervals, to ensure the dignity of the deceased is maintained. In addition, the establishment's procedure for checking and documenting the condition of bodies is not conducted for babies stored in the mortuary.	**Major**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Governance meetings where matters relating to HTA-licensed activities have not taken place regularly. Where these have taken place, they have not included persons designated (PD's) in other areas where licensed activity takes place. *This shortfall was identified at the previous inspection in 2018.*	**Major**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The scope of the audit schedule for licensed activities conducted under the licence is limited. The audit schedule does not include sufficient audits to check compliance with documented procedures, the completion of records or traceability of bodies. A document of HTA standards is in place to show which standards the audits are assessed against however, this document does not cross reference the applicable standards against the audits.	**Cumulative**

b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	The audit template used for both horizontal and vertical audits does not cover all areas of the procedure, or record sufficient detail to ensure that the audit is robust. Audit findings have not been investigated fully to understand the root cause of failures to comply with the establishment's procedures. Audit findings do not state who is responsible for the root cause analysis and implementing corrective actions.	**Major**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	The establishment does not have a formal training package in place to train contracted funeral directors and site practitioners that are involved in out of hours mortuary duties. The porters training package does not include the procedure for reporting HTA Reportable Incidents (HTARIs).	**Major**
c) Staff are assessed as competent for the tasks they perform	There is no competency assessments in place to assess and record the competency of contracted funeral directors and site practitioners in the tasks they perform.	**Major**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Portering and maternity staff are not aware of the HTARI reporting requirements that must be reported to the HTA or the procedure for reporting incidents. The incident SOP does not include the HTARI reporting categories and process for reporting incidents to the HTA. *This shortfall was identified at the previous inspection in 2018.* *See advice item 3.*	**Major**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		

a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	Not all procedures relating to licensed activities have been risk assessed. These include but are not limited to: • major equipment failure. • incidents leading to unplanned closure of mortuary/inability to deliver services. • serious security breach. • viewing of the wrong body. • release of the wrong body. This is not an exhaustive list of the risks not assessed and, to fully address this shortfall, the establishment should review all risk assessments relating to all licensed activities to ensure that all risks have been identified. On-call staff have access on their mobile phones to a CCTV camera in the porter body stores which shows the whiteboard containing deceased identifiers. This camera is checked by on-call staff on weekends and bank holidays to ensure that sufficient spaces are available for the portering staff to store the deceased. The establishment have not risk assessed this process and there is a risk to the dignity of the deceased .	**Cumulative Major**
b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	The establishment's risk assessments lack sufficient detail. They do not include what existing controls are in place and do not record any control measures that have been implemented to reduce the risk score. Several of the risks identified are categorised as high.	
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	Although staffing levels have been included on the Trust risk register, and a business case is being discussed to assess the needs of the mortuary, there is an immediate risk to staffing levels that needs to be considered given the level of activity undertaken at the establishment. *See shortfall under GQ1(c) for further detail.*	

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained	The mortuary is showing signs of wear and tear and requires maintenance to remain fit for purpose. There are multiple areas of damage to walls and doors leading to exposed porous plaster and wood. Areas around the drains in the PM examination room and body store are heavily rusted as well as the base of the refrigeration units. The area of the body store where the funeral directors enter has exposed porous brickwork. This means that these areas may be difficult to clean and adequately decontaminate. The inspection team found that the contingency units were not fit for purpose. The floor was wooden and buckling in places, the racks were rusty and the units have not been subject to regular cleaning due to the wooden flooring. These conditions could compromise the dignity of the deceased when in use.	**Major**
d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	Contingency refrigeration units are located on the Trust site near the satellite body store used by the porters. The containers are secured by scaffolding and padlocked gates only, and the doors to the units are secured only with padlocks. There is no CCTV covering either the gate or the doors to the contingency units . The inspection team noted that the scaffolding was in a state of disrepair. The external controls and power supply for the contingency units are accessible, leaving a risk of the external controls being tampered with when switched on. There are two satellite body stores used by the porters who transfer the deceased from the hospital wards. Although Trust CCTV is in place, the cameras are situated at a distance from the doors to the satellite body stores. There is a risk that the position of the CCTV cameras means they do not cover the entrance to the satellite body store. Due to a temporary unit erected in the viewing area, this has obscured the view of the CCTV camera for when families attend for a viewing.	**Major**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	During the inspection, the inspection team found that the funeral director's door had been left open, with no mortuary staff present in the body store. This door gives direct access to the body store from the outside, and there is a risk that Trust staff or members of the public could have accessed the mortuary. To demonstrate this, the inspection team were able to walk directly into the body store. Release of deceased can occur from the contingency units when they are in use, however the placement of the units prevents the funeral directors from reversing their vehicles fully into this area so the gate can be closed. As the gate has to remain open, there is a risk that unauthorised persons could view the movement of the deceased. This poses a risk to the dignity of the deceased.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The satellite body store is situated in a service area which is in full view of a service road and hospital offices. The area is frequented by Trust staff meaning the transfer of deceased, albeit on a covered trolley, is visible when porters bring deceased to the body store or when mortuary staff transfer deceased to the main body store. These storage arrangements pose a risk to the dignity of the deceased.	**Cumulative Major**
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	Although capacity for storage of bodies is reviewed on a regular basis, the establishment uses temporary units for prolonged periods of time outside of predicted times of peak activity.	
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	Due to the limited freezer storage facilities at both sites, bodies were identified as being held in refrigerated storage for longer than the HTA's recommended 30 days. The establishment has had a freezer unit recently installed to meet the long term storage needs, however this was not operational during the inspection. *The establishment confirmed prior to the final report being issued that the freezer unit was now in use.*	

i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	The establishment does not have a documented contingency plan in place should there be insufficient numbers of refrigerated storages spaces during peak periods.	
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The ventilation system has been serviced, however the report found that the minimum air changes per hour were not being meet. The establishment have been unable to provide an updated service report showing that the system is operating to the required standard. This poses a potential health and safety risk to all staff working in the mortuary.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
d) Staff have annual appraisals and personal development plans	Staff do not have annual appraisals.	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents	The SOP for reporting adverse incidents does not include the HTARI categories, who is responsible for the follow-up actions or who can report incidents in the DI's absence.	**Minor**
d) Information about incidents is shared with all staff to avoid repeat errors	Relevant information about incidents is not always shared with staff who undertake activities under the licence.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	The trolleys have multiple areas of rust. This means it is difficult for staff to adequately clean and disinfect this equipment.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice
The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ2(c)	The DI is advised to ensure that they receive a copy of the certificate of disposal of existing holdings of tissue blocks and slides held at an off-site establishment for assurance that disposal is being carried out within the contracted timeframe.
2.	GQ3(f)	The DI is advised to ensure that induction and competency assessment documents are fully completed with the dates of when the procedure was assessed.
3.	GQ5(a)	The DI is advised to have an aide-memoire in the main body store, the satellite body stores and maternity department showing the applicable HTARI categories and persons to contact if an incident should occur.
4.	GQ6(a)	The DI is advised to ensure that the risk of moving deceased out of the fridges from the floor scoops is risk assessed.
5.	T1(a)	The DI is advised to add a number to any unknown deceased that are admitted to the mortuary, especially if staff are unable to store the deceased in separate fridge or freezer banks due to capacity issues. This may help reduce the risk of transferring the wrong deceased for identification or PM examination.
6.	T1(d)	The DI is advised to place the same/similar name magnets on the whiteboard in the body store to increase the robustness of the current procedure.

7.	PFE1(a)	The DI is advised to ensure that the panic alarm cords in the family area are replaced.

Background

Croydon Health Services NHS Trust is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

Croydon Health Services NHS Trust has been licensed by the HTA since May 2008. This was the fourth inspection of the establishment; the most recent previous inspection took place in September 2018

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

Standards T2 (a), (b), (c) and (d) were not assessed as the establishment do not store tissue taken at post mortem examination. The remaining 68 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary and post-mortem room, records demonstrating the servicing of equipment, audits, risk assessments, ventilation record, temperature monitoring for the storage units, reported incidents and staff training records.

Visual inspection

The inspection included a visual inspection of the mortuary body stores, PM room and viewing room.

Audit of records

Audits were conducted for four bodies in refrigerated storage and one in long term storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and electronic database. Whilst one minor discrepancy was found, this was not sufficient to amount to a shortfall but oral advice was given to the establishment at the time of the inspection.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, trainee anatomical pathology technician, pathologist, portering staff and maternity staff.

Report sent to DI for factual accuracy: 18 September 2023

Report returned from DI: 2 October 2023

Final report issued: 6 November 2023

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 26 April 2024

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004 (HT Act) or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence
   - Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or

- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.